



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/589,866

09/19/2006

Herve Bercovier

27637U

2826

20529 7590 02/25/2009

THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314

EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

02/25/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/589,866

Applicant(s)

BERCOVIER ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 66-100 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 66-100 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Lack of Unity

- 1) Claims 1-65 have been canceled.

New claims 66-100 have been added.

Claims 66-100 are under prosecution.

- 2) As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (“requirement of unity of invention”). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression “special technical features” shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

- 3) As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specifically designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

- 4) Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 66-77 and 81-91, drawn to an amino acid molecule comprising a peptide capable of binding to ManLAM binding antibodies.
- II. Claims 78-80, drawn to a method for diagnosing a mycobacterial infection using an amino acid molecule comprising a peptide capable of binding to ManLAM binding antibodies.
- III. Claims 92-100, drawn to a method of immunization against mycobacterial infection comprising providing an amino acid molecule comprising a peptide capable of binding to ManLAM binding antibodies.

5) Inventions I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons. The special technical feature of the first claimed invention, for example of claim 1, is an amino acid molecule comprising a peptide capable of binding to ManLAM binding antibodies. However, such a product was already known in the art at the time of the invention. For example, Pompejus *et al.* (US 7,273,721, filed 6/25/1999) taught a protein molecule comprising the peptide VERWEKHT, which is 100% identical to the VERWEKHT peptide within the instantly recited amino acid molecule of SEQ ID NO: 5, which is expected bind to ManLAM antibodies.

Patent No. 7273721

GENERAL INFORMATION:

APPLICANT: Pompejus, Mark

APPLICANT: Kroger, Burkhard

APPLICANT: Schoder, Hartwig

APPLICANT: Zelder, Oskar

APPLICANT: Haberhauer, Gregor

TITLE OF INVENTION: CORYNEBACTERIUM GLUTAMICUM GENES ENCODING PROTEINS

TITLE OF INVENTION: INVOLVED IN MEMBRANE SYNTHESIS AND MEMBRANE

TITLE OF INVENTION: TRANSPORT

FILE REFERENCE: BGI-125CPCN

CURRENT APPLICATION NUMBER: US/10/627,476

CURRENT FILING DATE: 2003-07-25

PRIOR APPLICATION NUMBER: 09/602,787

PRIOR FILING DATE: 2000-06-23

PRIOR APPLICATION NUMBER: USSN 60/141031
PRIOR FILING DATE: 1999-06-25
NUMBER OF SEQ ID NOS: 678
SEQ ID NO 30
LENGTH: 568
TYPE: PRT
ORGANISM: Corynebacterium glutamicum

Query Match 66.7%; Score 48; DB 3; Length 568;
Best Local Similarity 100.0%; Pred. No. 20;
Matches 8; Conservative 0; Mismatches 0; Indels 0; Gaps 0.

QY 2 VERWEKHT 9
|||||||
Db 348 VERWEKHT 355

Therefore, the special technical feature of invention I does not define over the prior art.

Although the product of invention I, and the method of using the product of invention II or III is a permitted combination under PCT Rule 13.2, in the instant case, since the product of invention I is already disclosed in the art, the special technical feature is not a unifying feature.

Technically, the absence of special technical feature permits the separation of method of using the product or method of making the product from the product itself.

6) The Office has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be

amended during prosecution to require the limitations of the product claims. *Failure to do so may result in a loss of the right to rejoinder.* Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7) This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species identified below are structurally mutually exclusive.

(I) Peptide species: (a) SEQ ID NO: 1 (claims 76, 77, 90, 91, 99 and 100); (b) SEQ ID NO: 2 (claims 76, 90 and 99); (c) SEQ ID NO: 3 (claims 76, 90 and 99); (d) SEQ ID NO: 4 (claims 76, 90 and 99); and (e) SEQ ID NO: 5 (claims 76, 90 and 99). Claims 66-75, 81-89 and 92-98 are generic.

(II) Non-binding antibody species: (A) CS35 anti-LAM antibodies; (B) 735 anti-poly alpha(2->8) N-acetyl neuraminic acid mAb; and (C) 2H1 anti-glucuronoxylomannan mAb. See claims 71, 85 and 94. Claims 66-70, 72-77, 81-84, 86-93 and 95-100 are generic.

8) Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

Should applicant traverse on the ground that the inventions have unity of invention (37 CFR 1.475(a)), applicant must provide reasons in support thereof. Applicant may submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. Where such evidence or admission is provided

by applicant, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

10) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

11) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Mondesi, can be reached at (571) 272-0956.

/S. Devi/
Primary Examiner
AU 1645

February, 2009